REMARKS

In the Office Action dated May 19, 2000, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121 as follows:

Group I.	Claims 1-8 and 14-17, directed to an isolated nucleic acid molecule, vectors, host cells, a method of making a polypeptide and a pharmaceutical composition, classified in class 435, subclass 69.1.
Group II.	Claims 9-10 and 19-20, drawn to an isolated protein and a pharmaceutical composition, classified in class 530 subclass 350.
Group III.	Claims 12-13, drawn to an antibody, classified in class 530, subclass 387.1
Group IV.	Claim 21, drawn to a method of detecting OGFr expression using a nucleic acid, classified in class 435, subclass 6.
Group V.	Claim 22, drawn to a method of detecting OGFr expression using an antibody, classified in class 435, subclass 7.1.
Group VI.	Claim 23-24, drawn to a method of modulating cell growth *in vitro* using a nucleic acid, classified in class 514, subclass 44.
Group VII.	Claim 21, drawn to a method of promoting cell growth using an antibody, classified in class 514, subclass 2.
Group VIII.	Claim 26-37, drawn to a method of treating cancer, classified in class 514, subclass 44.

The Examiner has alleged that the subject matter defined by the claims of the present invention represents the foregoing eight separate and distinct inventions.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1-8 and 14-17, directed to an isolated nucleic acid molecule, vectors, host cells, a method of making a polypeptide and a pharmaceutical composition. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more <u>independent and distinct</u> inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent <u>and</u> distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In the first instance, Examiner has asserted that Groups I, II and III are independent and distinct from each other. The Examiner contends that the nucleic acid molecule of Group I, the protein of Group II and the antibody of Group III are products different in structure and function and that each product has independent and distinct utility.

Applicants respectfully submit that Groups I, II and III are clearly related, since the nucleic acid molecules of Group I code for and can be used to produce the polypeptides of Group II, and the antibodies of Group III are specific for the polypeptides of Group II. Thus, it is respectfully submitted that Groups I, II and III are not independent.

The Examiner also asserts that Group I and IV, VI, VIII, Groups III and V, VII are related as product and process of use, respectively. The Examiner contends that these groups are distinct inventions since the product can be used in a materially different process.

Applicants respectfully submit that Groups I and IV, VI, VIII are related, and that Groups III and V, VII are related, as the Examiner has conceded. Therefore, these groups are not independent of each other.

The Examiner further alleges that Groups I and V, VII, Groups II and IV-VIII, Groups III and IV, VI, VIII are unrelated, respectively, as these inventions are allegedly not disclosed as capable of being used together and have different modes of operation, different functions or effects. In addition, the

Examiner contends that Groups IV-VII are independent and distinct because the methods are practiced with materially different process steps for materially different purposes.

Applicants respectfully submit that these groups are all different aspects of a single invention. The methods of Groups IV-VIII merely teach how to make and use the nucleic acid molecules of Group I, the proteins of Group II which are encoded by the nucleic acid molecules of Group I, as well as the antibodies of Group III which are directed against the proteins of Group II.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter

and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which the Examiner associates another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in

response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional

application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

Frank S. DiGiglio
Registration No. 31,346

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

FSD/XZ:ab